

BREO ELLIPTA 100/25 and 200/25

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using BREO ELLIPTA?

BREO ELLIPTA contains the active ingredients fluticasone furoate and vilanterol (as trifenate). BREO ELLIPTA is used to treat asthma and chronic obstructive pulmonary disease (COPD).

For more information, see Section [1. Why am I using BREO ELLIPTA?](#) in the full CMI.

2. What should I know before I use BREO ELLIPTA?

Do not use if you have ever had an allergic reaction to BREO ELLIPTA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use BREO ELLIPTA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BREO ELLIPTA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use BREO ELLIPTA?

- The usual dose of BREO ELLIPTA for asthma and COPD is one inhalation 100 micrograms of fluticasone furoate and 25 micrograms of vilanterol once daily, at the same time each day.
- If you have severe asthma, your doctor may decide that you should use one inhalation of the higher strength BREO ELLIPTA inhaler (200 micrograms of fluticasone furoate and 25 micrograms of vilanterol). This strength is not suitable for COPD.

More instructions can be found in Section [4. How do I use BREO ELLIPTA?](#) in the full CMI.

5. What should I know while using BREO ELLIPTA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using BREO ELLIPTA.• Contact your doctor if you are concerned about any side effects.• Tell your doctor immediately if you become pregnant while using BREO ELLIPTA.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.• Do not take BREO ELLIPTA to treat any other complaints unless your doctor tells you to.• Do not give your medicine to anyone else, even if they have the same condition as you.• Do not take any other medicines for your breathing problems without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Take caution while driving or operating machinery until you know how BREO ELLIPTA affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store in the original package container to protect from moisture and do not open the foil lid until ready to inhale.• Keep your inhaler in a cool, dry place where the temperature stays below 30°C. If you store in a refrigerator, allow the inhaler to return to room temperature for at least an hour before use.

For more information, see Section [5. What should I know while using BREO ELLIPTA?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include oral fungal infection, influenza, common cold, voice disorders, headache, cough, pain and irritation in the back of the mouth and throat, itchy, runny or blocked nose, joint and back pain, muscle spasms, feeling anxious and disturbed sleep. Serious side effects include fever, pneumonia, bronchitis, inflammation of the sinuses, infection of the nose sinuses or throat, immediate breathing difficulties and wheezing, allergic reaction, osteoporosis, stomach pain, hyperglycaemia, irregular heartbeat, feeling depressed, increased irritability (mainly in children) and some long-term disorders.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

BREO ELLIPTA

Active ingredient(s): Fluticasone furoate 100 or 200 micrograms and vilanterol (as trifenate) 25 micrograms per inhalation

Consumer Medicine Information (CMI)

This leaflet provides important information about using BREO ELLIPTA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BREO ELLIPTA.**

Where to find information in this leaflet:

- [1. Why am I using BREO ELLIPTA?](#)
- [2. What should I know before I use BREO ELLIPTA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use BREO ELLIPTA?](#)
- [5. What should I know while using BREO ELLIPTA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using BREO ELLIPTA?

BREO ELLIPTA contains the active ingredients fluticasone furoate and vilanterol (as trifenate). Fluticasone furoate belongs to a group of medicines called corticosteroids, often simply called steroids. Vilanterol (as trifenate) belongs to a group of medicines called bronchodilators.

BREO ELLIPTA is used to treat asthma and chronic obstructive pulmonary disease (COPD).

Asthma is when the muscles surrounding the smaller airways become tight (bronchoconstriction), swollen, and irritated (inflammation). Symptoms come and go and include shortness of breath, wheezing, chest tightness and cough.

COPD is a long-term condition that slowly gets worse. Symptoms include shortness of breath, cough, chest discomfort and coughing up mucous. BREO ELLIPTA has been shown to reduce flare-ups of COPD symptoms.

Corticosteroids are used to reduce inflammation. They reduce the swelling and irritation in the small air passages in the lungs and can ease breathing problems. Corticosteroids also help to prevent attacks of asthma.

Bronchodilators relax the muscles of the small air passages in the lungs. This helps to open the airways and makes it easier for air to get in and out of the lungs. When it is taken regularly, it helps the small air passages to remain open.

When you take these two medicines together regularly, they will help to control your breathing difficulties.

BREO ELLIPTA should not be used to relieve a sudden attack of breathlessness or wheezing. If you get this sort of attack, you must use a quick-acting inhaler (such as VENTOLIN).

Your doctor may have prescribed BREO ELLIPTA for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 12 years.

2. What should I know before I use BREO ELLIPTA?

Warnings

Do not use BREO ELLIPTA if:

- you are allergic to fluticasone furoate, vilanterol, or any of the ingredients listed at the end of this leaflet.
- you are allergic to lactose or milk protein.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition.
- have been diagnosed with an intolerance to some sugars, or to milk protein.
- have liver disease, as you may be more likely to have side effects. If you have moderate or severe liver disease, your doctor will limit your dose to the lower strength of BREO ELLIPTA (100/25 micrograms once daily).
- have heart problems or high blood pressure.
- have ever been told you have diabetes or high blood sugar.
- are being or have ever been treated for tuberculosis (TB) or pneumonia.
- have weak bones (osteoporosis).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

BREO ELLIPTA is not usually recommended for use during pregnancy.

Your doctor will consider the benefit to you and the risk to your baby of taking BREO ELLIPTA while you are pregnant.

It is not known whether the ingredients of BREO ELLIPTA can pass into breast milk.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or

supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines may interfere with BREO ELLIPTA and affect how it works or make it more likely that you will have side effects.

These medicines include:

- Ketoconazole, to treat fungal infection.
- Ritonavir, to treat HIV infection.

Medicines that should be avoided:

- A class of medicines known as "beta-blockers" used to treat high blood pressure or a heart condition.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BREO ELLIPTA.

4. How do I use BREO ELLIPTA?

How much to use

- The usual dose of BREO ELLIPTA for asthma and COPD is one inhalation 100 micrograms of fluticasone furoate and 25 micrograms of vilanterol once daily at the same time each day.
- Follow the instructions provided and use BREO ELLIPTA until your doctor tells you to stop.
- If you have severe asthma, your doctor may decide that you should use one inhalation of the higher strength BREO ELLIPTA inhaler (200 micrograms fluticasone furoate and 25 micrograms of vilanterol).
- If you have moderate or severe liver disease, the maximum dose is one inhalation of BREO ELLIPTA (100 micrograms fluticasone furoate and 25 micrograms of vilanterol) once daily.

When to use BREO ELLIPTA

- Use BREO ELLIPTA regularly.
- It is very important that you use BREO ELLIPTA every day, as instructed by your doctor. This will help to keep you free of symptoms throughout the day and night.
- Use BREO ELLIPTA for as long as your doctor recommends. It will only be effective as long as you are using it. Do not stop unless your doctor advises you to, even if you feel better.

How to use the Ellipta

- To use BREO ELLIPTA, you breathe it into your lungs through your mouth using the Ellipta inhaler.
- The full instructions for using BREO ELLIPTA are given on a leaflet inside the pack.
- BREO ELLIPTA is ready to use straight away. No preparation or checks of the inhaler are required.
- Do not open BREO ELLIPTA until you are ready to use it for the first time.
- After using BREO ELLIPTA, you may clean the mouthpiece, using a dry tissue, before you close the cover. Do not immerse BREO ELLIPTA in water.

If you forget to use BREO ELLIPTA

BREO ELLIPTA should be used regularly at the same time each day. If you miss your dose at the usual time, use it as soon as you remember, then go back to using it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

- If you are not sure what to do, ask your doctor or pharmacist.
- If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you become wheezy or breathless, or develop any other symptoms of an asthma attack, use your quick-acting inhaler (e.g., VENTOLIN), then seek medical advice.

If you use too much BREO ELLIPTA

If you think that you have used too much BREO ELLIPTA, you may need urgent medical attention. You may notice that your heart is beating faster than usual, you feel shaky or have a headache.

You should immediately:

- phone the Poisons Information Centre (**by calling 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you have used larger doses than instructed for a long period of time, it is particularly important that you ask your doctor or pharmacist for advice. This is because larger doses of BREO ELLIPTA may reduce the amount of steroid hormones produced naturally by your body.

5. What should I know while using BREO ELLIPTA?

Things you should do

Call your doctor straight away if:

- you feel you are getting breathless or wheezy more often than normal, or if you are using your quick-acting inhaler more than usual.
- You experience blurred vision or other visual disturbances.
- You experience increased thirst, frequent urination, or unexplained tiredness (signs of high blood sugar).
- You experience fever, chills, increased mucous production, change in mucous colour, increased cough or increased breathing difficulties as these may be symptoms of pneumonia. Infection of the lungs (pneumonia) after using BREO ELLIPTA is common (it may affect up to 1 in 10 people).

Call your doctor straight away if you:

- become pregnant while taking this medicine.

Remind any doctor, dentist, or pharmacist you visit that you are using BREO ELLIPTA.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using BREO ELLIPTA.

Keep all of your doctor's appointments so that your progress can be checked.

Things you should not do

- Do not stop BREO ELLIPTA or lower the dosage without medical advice.
- Do not take BREO ELLIPTA to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not take any other medicines for your breathing problems without checking with your doctor.

Osteoporosis

- BREO ELLIPTA may cause weakening of the bones (osteoporosis) and increase your risk of fractures.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BREO ELLIPTA affects you.

Looking after your medicine

- Store in the original package container in order to protect from moisture and do not open the foil lid until ready to inhale.
- If you store your medicine in a refrigerator, allow the inhaler to return to room temperature for at least an hour before use.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat, or sunlight where the temperature stays below 30°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep it where young children cannot reach it.

When to discard your medicine

Safely discard BREO ELLIPTA one month after you open the foil tray or when your counter reads "0", whichever comes first. Write the date the inhaler should be discarded on the label in the space provided. The date should be added as soon as the inhaler has been removed from the tray.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

To reduce the chance of side effects, your doctor will prescribe the lowest effective dose of BREO ELLIPTA to control your asthma or COPD.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Infections and infestations: <ul style="list-style-type: none">• sore, raised patches in the mouth or throat caused by a fungal infection (<i>candidiasis</i>) Immune system: <ul style="list-style-type: none">• flu (influenza)• common cold Nervous system disorders: <ul style="list-style-type: none">• voice disorders• headache Respiratory, thoracic, and mediastinal disorders: <ul style="list-style-type: none">• cough• pain and irritation in the back of the mouth and throat• itchy, runny, or blocked nose Musculoskeletal and connective tissue disorders: <ul style="list-style-type: none">• joint and back pain• muscle spasms Gastrointestinal disorders: <ul style="list-style-type: none">• stomach pain Psychiatric disorders: <ul style="list-style-type: none">• feeling anxious• disturbed sleep	Speak to your doctor if you have any of these less serious side effects and they worry you. If you experience a fungal infection of the mouth or throat, rinsing your mouth out with water immediately after using BREO ELLIPTA may help stop this side effect developing.

Serious side effects

Serious side effects	What to do
General disorders: <ul style="list-style-type: none">• high temperature (fever)	Call your doctor straight away, or go straight to the

Serious side effects	What to do
<p>Respiratory, thoracic, and mediastinal disorders:</p> <ul style="list-style-type: none"> infection of the lungs (<i>pneumonia</i>). Symptoms include fever, chills, increased mucous production, change in mucous colour, increased cough or increased breathing difficulties. inflammation of the lungs (bronchitis) inflammation of the sinuses infection of the nose sinuses or throat immediate breathing difficulties and wheezing <p>Allergic reaction:</p> <ul style="list-style-type: none"> Symptoms of an allergic reaction usually include the following: <ul style="list-style-type: none"> wheezing swelling of the lips/mouth, tongue, or throat difficulty in breathing hay fever, lumpy rash (“hives”) fainting <p>Musculoskeletal and connective tissue disorders</p> <ul style="list-style-type: none"> weakening of the bones (osteoporosis), leading to risk of fractures <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> stomach pain <p>Metabolism and nutrition disorders:</p> <ul style="list-style-type: none"> increase in blood sugar (hyperglycaemia). This may lead to increased thirst, frequent urination, or unexplained tiredness. <p>Cardiac disorders:</p> <ul style="list-style-type: none"> irregular heartbeat <p>Psychiatric disorders:</p> <ul style="list-style-type: none"> feeling depressed increased irritability (mainly in children) <p>Long-term disorders in patients taking higher doses:</p> <ul style="list-style-type: none"> rounded face loss of bone density eye problems (e.g., cataract, glaucoma) slowing of growth in children. It is unclear what, if any, 	<p>Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>If your breathing or wheezing gets worse straight after using BREO ELLIPTA, stop using it immediately, and tell your doctor as soon as possible.</p>

Serious side effects	What to do
<p>difference this makes to a child's final height.</p>	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects via <https://nzphvc.otago.ac.nz/reporting/>

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What BREO ELLIPTA contains

Active ingredient (main ingredient)	Fluticasone furoate Vilanterol (as trifenate)
Other ingredients (inactive ingredients)	Lactose monohydrate Magnesium stearate
Potential allergens	Lactose or milk protein Fluticasone furoate Vilanterol (as trifenate)

Do not take this medicine if you are allergic to any of these ingredients.

What BREO ELLIPTA looks like

BREO ELLIPTA is inhaled through the mouth using the Ellipta device. The active substances are in separate blisters in powder form inside the device. There are 30 blisters on each strip, and so each device contains 30 doses.

The Ellipta device itself is a plastic inhaler with a light grey body, a pale blue mouthpiece cover and a dose counter. It is packaged in a foil laminate tray with a peelable foil lid. The tray contains a desiccant sachet, to reduce the moisture in the packaging. Once you have opened the lid of the tray, throw the desiccant away - do not open, eat, or inhale it.

BREO ELLIPTA fluticasone furoate 100 microgram / vilanterol (as trifenate) 25 microgram powder for inhalation (TT50-9114).

BREO ELLIPTA fluticasone furoate 200 microgram / vilanterol (as trifenate) 25 microgram powder for inhalation (TT50-9114a).

Who distributes BREO ELLIPTA

GlaxoSmithKline NZ Ltd
Private Bag 106600
Downtown
Auckland 1143
New Zealand

Phone: (09) 367 2900
Facsimile: (09) 367 2910

Trademarks are owned by or licensed to the GSK group of companies.

© 2024 GSK group of companies or its licensor.

This leaflet was prepared in September 2024.

Version 7.0